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510(k) Summary

MAY 10 2010

Submitter Information

Submitter's Name:	Riverpoint Medical
Address:	825 NE 25th Ave. Portland, OR 97232
Phone Number:	(503) 517-8001 or 866 445-4923
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Registration Number:	3006981798
Contact Person:	Douglas Rowley (503) 517-8001
Date of Preparation:	December 23rd, 2009

Device Name

Trade Name:	HS Fiber (Polyblend); RiverBond (Polyester); RiverSilk (Silk); RiverPro (Polypropylene); RiverLon (Nylon)
Common Name:	Non-absorbable Surgical Sutures: Polyblend, Polyester, Silk Polypropylene, Nylon
Classification Name:	All: General and Plastic Surgery Device

Device Classification

FDA Class: 2 (All varieties)

Product Classification:

1. Polyblend: 878.5000, Nonabsorbable poly(ethylene terephthalate) surgical suture
2. Polyester: 878.5000, Nonabsorbable poly(ethylene terephthalate) surgical suture
3. Silk: 878.5030, Natural Nonabsorbable silk surgical suture
4. Polypropylene: 878.5010, Nonabsorbable polypropylene surgical suture
5. Nylon: 878.5020, Nonabsorbable polyamide surgical suture

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Code:

1.	Polyblend Suture:	GAT
2.	Polyester Suture:	GAS
3.	Silk Suture:	GAP
4.	Polypropylene Suture:	GAW
5.	Nylon Suture:	GAR

Classification Panel: All: Class II (special controls); General and Plastic Surgery

Predicate Devices (applicable 510(k) number listed)

1. Polyblend Suture: Teleflex® Force Fiber® (K063778)
2. Polyester Suture: Genzyme Biosurgery® (K021019)
3. Silk Suture: Sherwood-Davis & Geck® (K982853)
4. Polypropylene Suture: US Surgical® (K050947)
5. Nylon Suture: CP Medical® (K001173)

Special Controls

FDA Guidance "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA" was followed during the preparation of this submission.

Device Description

Riverpoint Medical non-absorbable surgical sutures are medical devices used to secure tissues together or create wound closures during a surgical procedure or after an injury. They are composed of the applicable suture material and a standard medical grade suture needle as applicable (sutures can be provided without needles as well). See table below for additional information about each applicable suture material included in this submission.

Available Suture sizes will be standard according to USP 32 requirements (12/0 through 7, depending on suture type).

Intended Use

RiverBond, RiverSilk, RiverPro, and RiverLon non-absorbable sutures are intended to be used for soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures.
HS Fiber non-absorbable suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular procedures, and the use of allograft tissue for orthopedic procedures.

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Safety and Effectiveness

Each variety of Riverpoint Medical non-absorbable sutures has been designed and manufactured to be substantially equivalent to the predicate devices listed for safety and effectiveness. Materials used were selected based on known biocompatibility and established histories of use in the medical device industry for implantable devices, and are identical or substantially equivalent to the materials used in the predicate devices listed.

Riverpoint Medical non-absorbable sutures have been designed to meet the requirements for diameter, tensile strength, and needle attachment strength as specified within USP 32. Testing is performed on each lot of product to verify that USP requirements have been met prior to release.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Riverpoint Medical
% Mr. Doug Rowley
RA/QA Manager
825 NE 25th Avenue
Portland, Oregon 97232

MAY 10 2010

Re: K100006
Trade/Device Name: Polyester Non-absorbable Surgical Suture, Polyblend Non-absorbable Surgical Suture, Silk Non-absorbable Surgical Suture, Polypropylene Surgical Suture, Nylon Non-absorbable Surgical Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT, GAS, GAP, GAW, GAR
Dated: April 1, 2010
Received: April 16, 2010

Dear Mr. Rowley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: Unknown at this time K100006

Device Name: Polyester Non-absorbable Surgical Suture

Trade Name: RiverBond

Indications for Use:

RiverBond surgical suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurosurgical procedures. RiverBond suture is provided sterile as a single use device.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krome for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100006

Indications for Use Statement

510(k) Number: K100006

Device Name: Polyblend Non-absorbable Surgical Suture

Trade Name: HS Fiber

Indications for Use:

Hs Fiber surgical suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular procedures, and the use of allograft tissue for orthopedic procedures.
HS Fiber suture is provided sterile as a single use device.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100006

Indications for Use Statement

510(k) Number: Unknown at this time K100006

Device Name: Silk Non-absorbable Surgical Suture

Trade Name: RiverSilk

Indications for Use:

RiverSilk surgical suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurosurgical procedures.
RiverSilk suture is provided sterile as a single use device.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K100006

Indications for Use Statement

510(k) Number: Unknown at this time K100006

Device Name: Polypropylene Non-absorbable Surgical Suture

Trade Name: RiverPro

Indications for Use:

RiverPro surgical suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurosurgical procedures.
RiverPro suture is provided sterile as a single use device.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100006

Indications for Use Statement

510(k) Number: Unknown at this time K100006

Device Name: Nylon Non-absorbable Surgical Suture

Trade Name: RiverLon (monofilament) and RiverLon Braid (braided)

Indications for Use:

RiverLon and RiverLon Braid surgical suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurosurgical procedures.
RiverPro suture is provided sterile as a single use device.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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510(k) Number K100006